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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,818	01/26/2004	Patricia A. Brown	108328.00170 (AVSI-0033)	8276
70225	7590	12/07/2007	EXAMINER	
JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202			SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			12/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/764,818	BROWN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-9, 11, 17-19, 22, 23, 26-28, 30, 35-38, 41-45, 47, 48 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 11, 17-19, 22, 23, 26-28, 30, 35-38, 41-45, 47, 48, and 53-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

An amendment was received and entered on 10/30/07.

Claims 12-15, 31-34, 40, 49-52, 57, 63, 69, 75, 77, 79, 80, 86, 89, 97, and 99- were canceled.

Claims 1-4, 7-9, 11, 17-19, 22, 23, 26-28, 30, 35-38, 41-45, 47, 48, and 53-56 remain pending and are under consideration.

### ***Rejections Withdrawn***

Rejections not reiterated from the previous action are withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17, 23, 26-28, 30, 35-38, 41-43 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 17 are indefinite because they depend from canceled claim 15.

Claims 23, 26-28, 30, 35-38, and 41-43 are indefinite because it is unclear what is intended by the phrase "days after elapse of time" such that one of skill in the art cannot understand when the method requires re-evaluation of body condition score. It is unclear what amount of time is meant to have elapsed.

Claims 35 and 36 are indefinite because they depend from canceled claim 34.

Claims 53 and 54 are indefinite because they depend from canceled claim 52.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-9, 11, 18, 19, 22, 44, 45, 47, 48, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al (WO 200261037 A2) in view of Aihara et al (Nature Biotech. 16: 867-870, 1998) and Simon (US 6,928,318), and Allaire et al (Livestock Prod. Sci. 7(4): 349-360, 1980).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Schwartz taught methods of increasing milk production in farm animals such as cows by injection into muscle of the animal of an expression vector encoding growth hormone releasing hormone (GHRH). See paragraph 23 on page 12. GHRH expression vectors for use included pSPc5-12-HV-GHRH (instant SEQ ID NO:11), see e.g. paragraph 124 on page 34. Vectors were delivered by injection into muscle and subsequent electroporation by the method of Aihara. See paragraph bridging pages 37 and 38, and paragraph 168 on page 52. Aihara taught a method of electroporating nucleic acids into muscle by inserting electrode needles into muscle such that they encompassed the site into which DNA is injected. See page 867, column 2, second full paragraph. So, it is clear that the method of Schwartz includes delivery of nucleic acid to an area of tissue that is surrounded by and penetrated with a plurality of needles.

Schwartz did not teach application of a constant current electrical pulse.

Simon taught an electroporation system for introducing nucleic acids into muscle that utilizes a constant-current pulse generator where the delivered current is constant and substantially independent of a change in a resistance in the selected tissue. See specifically column 12 lines 17-51, and column 18, lines 55-58.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the electroporation of Simon because it allows such advantages as enabling accurate measurement and recording of the entire time course of relevant

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electrical parameters during electroporation. This facilitates optimization of conditions.

See column 18, lines 14-22.

With regard to limitations requiring a reduction in mortality of newborns (claims 3 and 4) note that Schwartz envisioned methods of delivery to pregnant farm animals.

See paragraphs 15-22 at pages 6-12.

The combination of Schwartz, Aihara, and Simon does not disclose a process of culling farm animals from a group of farm animals comprising the steps of both voluntary and involuntary culling.

Allaire et al studied the effect of voluntary culling on low milk yield and economic return for herds with a stable number of milk cows. Allaire taught that the voluntary culling of dairy cattle up to 3-8 percentage units above involuntary cow replacement rate maximizes economic returns per cow in herd when market price for replacement heifers exceeds 150% of their beef value, and that maximum voluntary culling may be practiced for prices near or below beef value.

One of ordinary skill in the art appreciates that involuntary culling (i.e. culling due to death, disease, or dry off) is an inherent characteristic of dairy farming. In view of the teachings of Allaire, it was routine in the art at the time of the invention to practice voluntary culling in dairy herds, and it would have been obvious to one of ordinary skill in the art to perform voluntary culling on any dairy herd, including one that had been treated by the method of Schwartz as modified by Simon, in order to maximize milk yield and economic return. In view of the teachings of Allaire it was also obvious to measure milk production of each cow over its lifetime. Accordingly it would have been

obvious to measure milk production both before and after injection of GHRH-encoding plasmid, particularly in view of the fact that Schwartz taught that such injection was meant to increase milk production.

Claims 23, 26-28, 30, 37, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al (WO 200261037 A2) in view of Aihara et al (Nature Biotech. 16: 867-870, 1998), Simon (US 6,928,318), and Bontempo et al (Schriftenreihe - Forschungsinstitut fuer die Biologie Landwirtschaftlicher Nutztiere (1994), 4(VIth International Symposium on Digestive Physiology in Pigs, 1994, Vol. 2), 360-361).

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that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Schwartz taught methods of increasing milk production in farm animals such as cows by injection into muscle of the animal of an expression vector encoding growth hormone releasing hormone (GHRH). See paragraph 23 on page 12. GHRH expression vectors for use included pSPc5-12-HV-GHRH (instant SEQ ID NO:11), see e.g. paragraph 124 on page 34. Vectors were delivered by injection into muscle and subsequent electroporation by the method of Aihara. See paragraph bridging pages 37 and 38, and paragraph 168 on page 52. Aihara taught a method of electroporating nucleic acids into muscle by inserting electrode needles into muscle such that they encompassed the site into which DNA is injected. See page 867, column 2, second full paragraph. So, it is clear that the method of Schwartz includes delivery of nucleic acid to an area of tissue that is surrounded by and penetrated with a plurality of needles.

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Simon taught an electroporation system for introducing nucleic acids into muscle that utilizes a constant-current pulse generator where the delivered current is constant and substantially independent of a change in a resistance in the selected tissue. See specifically column 12 lines 17-51, and column 18, lines 55-58.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the electroporation of Simon because it allows such advantages as enabling accurate measurement and recording of the entire time course of relevant

electrical parameters during electroporation. This facilitates optimization of conditions.

See column 18, lines 14-22.

Limitations concerning the mass of nucleic acid construct administered are obvious because the mass of nucleic acid construct administered is a result effective variable. See paragraph 140 on page 40 of Schwarz.

Schwarz, Aihara, and Simon were silent regarding body condition scores. However, Bontempo measured the effects on sows of a dietary additive, and chose body condition score as a direct variable. This indicates that it was routine in the art at the time of the invention to measure body condition score to determine the effects of treatments on pigs. Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to determine the body condition score of pigs before and after the administration of expression vectors encoding GHRH in order to determine the effects of the treatment on pig growth and health.

Claims 23, 26-28, 30, 37, 38, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al (WO 200261037 A2) in view of Aihara et al (Nature Biotech. 16: 867-870, 1998), Simon (US 6,928,318), and Encinias et al (2000) (retrieved from <http://www.ag.ndsu.edu/pubs/ansci/beef/as1026.pdf>).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Schwartz taught injection of pSPc5-12-HV-GHRH (SEQ ID NO:11) into the muscle of a farm animal, and subsequent electroporation at the site by the method of Aihara. Pigs are exemplified at the paragraph bridging pages 37 and 38. Other animals include dairy cows, see paragraph 23. Aihara taught a method of electroporating nucleic acids into muscle by inserting electrode needles into muscle such that they encompassed the site into which DNA is injected. See page 867, column 2, second full paragraph. So, it is clear that the method of Schwartz includes delivery of nucleic acid to an area of tissue that is surrounded by and penetrated with a plurality of needles.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to use the electroporation of Simon because it allows such advantages as enabling accurate measurement and recording of the entire time course of relevant electrical parameters during electroporation. This facilitates optimization of conditions. See column 18, lines 14-22.

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Schwarz, Aihara, and Simon were silent regarding body condition scores. However, Encinias taught that body condition scoring of cattle can be an effective management tool for evaluating the energy reserves of cows and the whole nutritional program throughout the year. Encinias stated that body condition scores "allow producers, extension personnel, and researchers to communicate more effectively regarding the herd's status." Accordingly it would have been obvious to one of ordinary skill in the art to measure body condition before and after administration of expression vectors encoding GHRH, in order to evaluate the benefits of the procedure on the cattle.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-9, 11, 18, 19, 22, 44, 45, 47, 48, 55, and 56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 of U.S. Patent No. 6,423,693, in view of Schwartz et al (US Patent 6,551,996), Simon (US 6,928,318), and Allaire et al (Livestock Prod. Sci. 7(4): 349-360).

Claims 21-23 of '693 are drawn to methods of delivering to muscle cells in vivo an expression vector encoding GHRH, wherein the vector comprises 5' and 3' UTRs. The portion of the specification supporting the claims indicates that method is intended for livestock improvement. See column 3, lines 8 and 9, and column 35, lines 20-41.

The '693 patent does not claim a synthetic muscle specific promoter or constant current electroporation.

The '996 patent taught a method of injecting into muscle of a farm animal a plasmid vector encoding SEQ ID NO:1 (HV-GHRH, an optimized protease resistant form of GHRH) under the control of a synthetic muscle specific promoter (SPc5-12).

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The site of injection was subsequently subjected to electroporation. See column 6, lines 15-24, column 22, lines 10-30. The method is intended to improve growth performance and increase the efficiency of the animal. See abstract, column 8, lines 24-60, and column 17, lines 31-34.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the promoter of '996 in the method of '693. One would have been motivated to do so because '996 taught that the SPc5-12 promoter greatly exceeds the transcriptional potencies of natural muscle specific promoters. See column 3, lines 45-50.

Simon taught an electroporation system for introducing nucleic acids into muscle that utilizes a constant-current pulse generator where the delivered current is constant and substantially independent of a change in a resistance in the selected tissue. See specifically column 12 lines 17-51, and column 18, lines 55-58.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the electroporation of Simon because it allows such advantages as enabling accurate measurement and recording of the entire time course of relevant electrical parameters during electroporation. This facilitates optimization of conditions. See column 18, lines 14-22.

The combination of the '693 patent, the '996 patent, and Simon does not disclose a process of culling farm animals from a group of farm animals comprising the steps of both voluntary and involuntary culling.

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Allaire et al studied the effect of voluntary culling on low milk yield and economic return for herds with a stable number of milk cows. Allaire taught that the voluntary culling of dairy cattle up to 3-8 percentage units above involuntary cow replacement rate maximizes economic returns per cow in herd when market price for replacement heifers exceeds 150% of their beef value, and that maximum voluntary culling may be practiced for prices near or below beef value.

One of ordinary skill in the art appreciates that involuntary culling (i.e. culling due to death, disease, or dry off) is an inherent characteristic of dairy farming. In view of the teachings of Allaire, it was routine in the art at the time of the invention to practice voluntary culling in dairy herds, and it would have been obvious to one of ordinary skill in the art to perform voluntary culling on any dairy herd, including one that had been treated by the method of Schwartz '693 as modified by Schwartz '996 and Simon, in order to maximize milk yield and economic return. In view of the teachings of Allaire it was also obvious to measure milk production of each cow over its lifetime. Accordingly it would have been obvious to measure milk production both before and after injection of GHRH-encoding plasmid, particularly in view of the fact that Schwartz taught that such injection was meant to increase milk production.

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Landwirtschaftlicher Nutztiere (1994), 4(VIth International Symposium on Digestive Physiology in Pigs, 1994, Vol. 2), 360-361).

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The '693 patent does not claim a synthetic muscle specific promoter or constant current electroporation.

The '996 patent taught a method of injecting into muscle of a farm animal a plasmid vector encoding SEQ ID NO:1 (HV-GHRH, an optimized protease resistant form of GHRH) under the control of a synthetic muscle specific promoter (SPc5-12). The site of injection was subsequently subjected to electroporation. See column 6, lines 15-24, column 22, lines 10-30. The method is intended to improve growth performance and increase the efficiency of the animal. See abstract, column 8, lines 24-60, and column 17, lines 31-34.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to use the electroporation of Simon because it allows such advantages as enabling accurate measurement and recording of the entire time course of relevant electrical parameters during electroporation. This facilitates optimization of conditions. See column 18, lines 14-22.

The '693 patent, the '996 patent, and Simon were silent regarding body condition scores. However, Bontempo measured the effects on sows of a dietary additive, and chose body condition score as a direct variable. This indicates that it was routine in the art at the time of the invention to measure body condition score to determine the effects of treatments on pigs. Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to determine the body condition score of pigs before and after the administration of expression vectors encoding GHRH in order to determine the effects of the treatment on pig growth and health.

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Biologie Landwirtschaftlicher Nutztiere (1994), 4(VIth International Symposium on Digestive Physiology in Pigs, 1994, Vol. 2), 360-361).

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### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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A handwritten signature in black ink, appearing to read 'R. Schnizer', with a long horizontal flourish extending to the right.

Richard Schnizer, Ph.D.  
Primary Examiner  
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